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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,742	07/24/2000	VSEVOLOD NIKOLAEVICH RUDIN	H970M1412US	9841
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M ROBERT KESTENBAUM 11011 BERMUDA DUNES NE ALBUQUERQUE, NM 87111				
		EXAMINER KRASS, FREDERICK F		
		ART UNIT PAPER NUMBER		
		1614 20		
DATE MAILED: 05/06/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,742

Applicant(s)

RUDIN ET AL.

Examiner

Frederick F. Krass

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P r i d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 1-3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Pri rity under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Formalities

1) Applicant is requested to amend the first line of the specification to read:

--- This application is a 371 of PCT/IB97/01634, filed 10/17/97. ---

2) Claim 8, while not indefinite *per se*, could benefit from revision. Specifically:

a) the term "substance of the group consisting of" at the second line of the claim should be amended to recite standard Markush language, i.e. --- substance selected from the group consisting of ---;

b) the term "bindings" at the fourth line of the claim should read --- binders--; and

c) the terms "Surfactants" and "Flavours" at the last line of the claim should be placed in the lower case.

3) Similarly, in claim 9, "at least one of the group" should be amended to read --- member selected from the group consisting of ---

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite without knowing which method of measurement was used. Honeywell Intl., Inc. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). Accordingly, the instantly claimed "average particle size" values (recited throughout the claims) are indefinite without the concurrent recitation of their method of measurement, i.e. by light scattering, by volumetric determination, by centrifugation, etc.

2) The term "ultra finely" in claims 5, 6 and 7 is a relative term which renders the claims indefinite. The term "ultra finely" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification provides no guidance for determining when a given particle size is sufficiently small to fall within the scope of the claimed term, and when a given particle size is sufficiently large to fall outside of it.

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3) Claims 6 and 8, the percent by weight values recited therein are indefinite for the same reasoning outlined in subsection "1)" supra, i.e. the basis on which the value is computed is not specified (based on total weight of the composition, based on total weight of carrier, based on the total weight of all particulate components in the composition, etc). This rejection can be obviated by reciting the basis for calculation, e.g. amending the last line of claim 6 to read --- 50% by weight, based on the weight of the stomatic composition ---

4) Claim 9, second line, the meaning of "enhancing the gingivitis system of the mouth cavity" is entirely unclear. (What is a "gingivitis system"?). Similarly, the term "gingivitis systems" at claim 11, line 4 is indefinite. The examiner recommends changing the claims to recite "gingivitis treating agents" instead.

5) Claim 9, fourth line, the scope of the open-ended term "etc." is not clear. One cannot determine from this term what additional ingredients are contemplated, nor which might be excluded. The term should be deleted.

6) Claim 9, last line, "the aqueous" and "the aqueous-alcoholic", respectively, lack antecedent basis. The examiner recommends reciting "an aqueous" and "an aqueous-alcoholic", as is done in claim 11, instead.

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Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 10-12, 14, 16, 17 and 19-21 of USP 6,254,855.

The previous examiner's obviousness-type double patenting rejection was not unreasonable. The instant and conflicting claims recite substantially the same hydroxapatite particles, and compositions containing them. Applicant has previously argued that USP 6,254,855 does not fairly suggest, teach or disclose the instantly claimed thicknesses, but this position is inconsistent with following admission which is made in the instant specification:

US Patent 6,254,855 column 2, line 30 to column 4, line 35 which is based upon WO 98/18719 (of the same inventor) are hereby incorporated by reference into the present application. The pages of US Patent 6,254,855 describe a method for producing a suspension as described in this application.

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Since the instant particles are produced by the very same method as those of the conflicting patent, they must inherently possess the same characteristics, including thickness.

Since the instantly claimed compositions are used as dentrifies, it would have been obvious to have formulated them into conventional dentrifice forms such as aqueous rinses, toothpastes, chewing gums, etc., where required by the conflicting claims. The motivation for doing so arises from the commercial realities of the marketplace, i.e. certain consumers prefer particular dentrifice forms over others, and it would have been obvious from an economic standpoint to have provided a variety of forms in order to tailor to each sub-group.

Where specific concentrations are recited in the conflicting claims (e.g. 7 to 96 percent in claim 1 of the patent), it is well-settled that "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003). Accordingly, it would have been obvious to have optimized the hydroxyapatite concentrations of the stomatic compositions of the instant claims to be within the scope of the conflicting claims which recite such specified concentrations, consonant with the reasoning of such precedent.

Regarding instant claims 9-11, since the conflicting compositions are used as dentrifies, it would have been obvious in a self-evident manner to have included various commercially available anti-microbial or anti-plaque agents, including plant extracts such as aqueous salvia extracts therein, motivated by the reasonable

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expectation of obtaining their expected effects, i.e. to aid oral hygiene by increasing anti-microbial/anti-plaque activity. (As factual support for the examiner's assertion that such is well-known see USP 6,027,716, cited herein on the attached Form 892, at col. 2, line 52).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 6:30-3:00PM;
Tuesday: 10-6:30PM;
Wednesday: off;
Thursday: 10-6:30PM; and
Friday: 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seidel Marianne, can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Frederick Krass', written in a cursive style.